510(K) SUBMISSION - MAXXIM MEDICAL SENSICARE™ SYNTHETIC POWDER-FREE SURGICAL GLOVES

K002933

OCT 1 9 2000

September 14, 2000

Maxxim Medical, Inc.
10300 49th Street North
Clearwater, FL 33762
Phone: 727-561-2100
Fax: 727-561-2180

510(K) SUMMARY OF SAFETY AND EFFICACY -
SENSICARE™ SYNTHETIC POLY-ISOPRENE POWDER-FREE SURGICAL GLOVES
Classification Name: Surgeon Glove, Type 2 (21 CFR 878.4460)

The device in this 510(k) submission is the SensiCare™ Synthetic Powder-Free Surgical Glove (Classification number 79KGO). The SensiCare™ Synthetic Powder-Free Surgical Glove is a sterile, synthetic rubber latex surgical glove. These gloves are intended to be used as a barrier by providing protection for surgical personnel and patients against microbial migration and to protect a surgical wound from contamination.

The SensiCare™ Synthetic Powder-Free Surgical Glove are substantially equivalent to the SensiCare™ Synthetic Powder-Free Surgical Glove previously submitted and cleared under 510(k) number K983982. The only difference is that this submission is for the inclusion of a chlorination step within the manufacturing process. The safety and effectiveness of the device is maintained. The results of the safety, efficacy, and performance testing of the SensiCare™ Synthetic Powder-Free Surgical Glove are detailed in this 510(k) submission and are summarized as follows:

1. The gloves meet all ASTM D3577-00, requirements for sterility, freedom from holes, physical properties, and physical dimensions. The gloves meet the requirements of 21 CFR 800.20 for freedom from pinholes.

2. The gloves have been tested and have been shown to be non-irritating and non-sensitizing under test conditions when evaluated in accordance with internationally recognized test methods.

3. The gloves have been tested per ASTM D6124-00, and are labeled as powder-free.

If you have any questions, please contact me at (864) 369-7391. I can also be reached at the following address:

Pallie V. Stoddard
Maxxim Medical
308 Church Street
Honea Path, SC 29654

Sincerely,

Pallie V. Stoddard
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

Ms. Pallie V. Stoddard
Quality Assurance Manager
Maxxim Medical
308 Church Street
Honea Path, South Carolina 29654

Re: K002933
Trade Name: Sterile SensiCare™ Synthetic Polyisoprene Powder-Free Surgical Gloves
Regulatory Class: I
Product Code: KGO
Dated: September 14, 2000
Received: September 20, 2000

Dear Ms. Stoddard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) SUBMISSION - MAXXIM MEDICAL SENSICARE™ SYNTHETIC POWDER-FREE SURGICAL GLOVES

INDICATIONS FOR USE

Applicant: Maxxim Medical, Inc.

510(k) Number: K002933

Device Number: Maxxim Medical Sensicare™ Synthetic POLYISOPRENE Powder-Free Surgical Gloves, STERILE

Indications for Use:

A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ Over-The Counter X
Per 21 CFR 801.109

Olin S. Lin
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002933